



IFW

PATENT  
Docket No.: 20747/320 (ARDBW/P31750US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Best et al.	)	Examiner:
Serial No.	:	10/576,437	)	To Be Assigned
Cnfrm. No.	:	To Be Assigned	)	Art Unit:
Filed	:	October 19, 2004	)	To Be Assigned
For	:	COMPOSITIONS AND METHODS OF TREATMENT	)	
			)	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.97-1.98

**Mail Stop: Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicants hereby bring to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-9) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 10-61) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

Respectfully submitted,

Date: October 25, 2006

  
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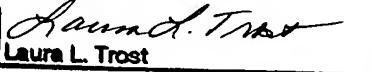
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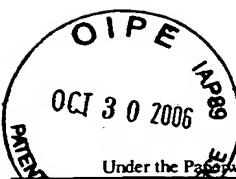
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10/26/06

Date

Laura L. Trost





<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>			
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Sheet	1	of	5	Attorney Docket Number	20747/320 (ARDBW/P31750US)		
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		Number - Kind Code <sup>2</sup> (if known)					
1	US-4,127,612		11-28-1978	Kluender et al.			
2	US-5,229,496		07-20-1993	Deeley et al.			
3	US-5,391,485		02-21-1995	Deeley et al.			
4	US-5,393,870		02-28-1995	Deeley et al.			
5	US-5,602,007		02-11-1997	Dunn et al.			
6	US-5,908,829		06-01-1999	Kelly			
7	US-6,127,378		10-03-2000	Gutterer			
8	US-6,280,718 B1		08-28-2001	Kaufman et al.			
9	US-6,458,589 B1		10-01-2002	Rambhatla et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)					
10	EP 1 097 922 A1		05-09-2001	Ono Pharmaceutical Co., Ltd.			
11	EP 1 114 816 A1		07-11-2001	Ono Pharmaceutical Co., Ltd.			
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>							
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	12	BELL, "Transplantation. Privileged Beginnings," <i>Nature Reviews Immunology</i> 2:75 (2002)					
	13	BRAUN et al., "Cholera Toxin Suppresses Interleukin (IL)-12 Production and IL-12 Receptor $\beta$ 1 and $\beta$ 2 Chain Expression," <i>J. Exp. Med.</i> 189:541-552 (1999)					
	14	BUCHSEL et al., "Granulocyte Macrophage Colony-Stimulating Factor: Current Practice and Novel Approaches," <i>Clin. J. Oncol. Nurs.</i> 6(4):198-205 (2002)					
	15	BURZYN et al., "Decrease in cAMP Levels Modulates Adhesion to Fibronectin and Immunostimulatory Ability of Human Dendritic Cells," <i>J. Leukoc. Biol.</i> 72:93-100 (2002)					
	16	CANTRELL et al., "Cloning, Sequence, and Expression of Human Granulocyte/Macrophage Colony-Stimulating Factor," <i>Proc. Natl. Acad. Sci. USA</i> 82:6250-6254 (1985)					
	17	DOUSA, "Cyclic-3',5'-Nucleotide Phosphodiesterase Isozymes in Cell Biology and Pathophysiology of the Kidney," <i>Kidney International</i> 55:29-62 (1999)					
	18	DRUKKER et al., "Characterization of the Expression of MHC Proteins in Human Embryonic Stem Cells," <i>Proc. Natl. Acad. Sci. USA</i> 99(15):9864-9869 (2002)					
Examiner Signature		Date Considered					

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup>Applicant's unique citation designation number (optional). <sup>3</sup>See Kinds Codes of USPTO Patent Documents at 222.uspto.gov or MPEP 901.04. <sup>4</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>7</sup>Applicant is to place a check mark here if English language Translation is attached.

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<p>Substitute for form 1449B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				<b>Complete if Known</b>			
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<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>							
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	19	EFRAT, "Cell Replacement Therapy for Type 1 Diabetes," <i>Trends Mol. Med.</i> 8:334-339 (2002)					
	20	FÄNDRICH et al., "Preimplantation-Stage Stem Cells Induce Long-Term Allogeneic Graft Acceptance Without Supplementary Host Conditioning," <i>Nature Med.</i> 8:171-178 (2002)					
	21	GENBANK ACCESSION NO. NM_000758 (01-OCT-2006)					
	22	GOERDT & ORFANOS, "Other Functions, Other Genes: Alternative Activation of Antigen-Presenting Cells," <i>Immunity</i> 10:137-142 (1999)					
	23	GRANT et al., "PGE/cAMP and GM-CSF Synergise to Induce a Pro-Tolerance Cytokine Profile in Monocyte Cell Lines," <i>Biochem. Biophys. Res. Comm.</i> 331:187-193 (2005)					
	24	HAMILTON et al., "GM-CSF in Inflammation and Autoimmunity," <i>Trends Immunol.</i> 23(8):403-408 (2002)					
	25	HANIFIN et al., "Type 4 Phosphodiesterase Inhibitor Have Clinical and <i>In Vitro</i> Anti-Inflammatory Effects in Atopic Dermatitis," <i>J. Invest. Dermatol.</i> 107:51-56 (1996)					
	26	HARIZI et al., "Cyclooxygenase-2-Issued Prostaglandin E <sub>2</sub> Enhances the Production of Endogenous IL-10, Which Down-Regulates Dendritic Cell Functions," <i>J Immunol.</i> 168:2255-2263 (2002)					
	27	HATA et al., "Granulysin Blocks Replication of Varicella-Zoster Virus and Triggers Apoptosis of Infected Cells," <i>Viral Immunol.</i> 14:125-133 (2001)					
	28	HAYASHIDA et al., "Antiinflammatory Effects of Colforsin Daropate Hydrochloride, a Novel Water-Soluble Forskolin Derivative," <i>Ann. Thoracic Surgery</i> 71:1931-1938 (2001)					
	29	HOLT et al., "MHC Class II Antigen-Bearing Dendritic Cells in Pulmonary Tissues of the Rat," <i>J. Exp. Med.</i> 167:262-274 (1988)					
	30	KALIŃSKI et al., "Dendritic Cells, Obtained from Peripheral Blood Precursors in the Presence of PGE <sub>2</sub> , Promote Th2 Responses," <i>Adv. Exp. Biol.</i> 417:363-367 (1997)					
	31	KAMBAYASHI et al., "Cyclic Nucleotide Phosphodiesterase Type IV Participates in the Regulation of IL-10 and in the Subsequent Inhibition of TNF- $\alpha$ and IL-6 Release by Endotoxin-Stimulated Macrophages," <i>J. Immunol.</i> 155:4909-4916 (1995)					
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	32	KELLY, "Shooting for the Moon. Bolstered by a New Research Agenda, Parkinson's Disease Researchers Aim High," <i>Neurology Reviews.com</i> 9(7):1-8 (2001) at <a href="http://www.neurologyreviews.com/jul01/nr_jul01_pd.html">http://www.neurologyreviews.com/jul01/nr_jul01_pd.html</a>					
	33	KRENSKY, "A Novel Antimicrobial Peptide of Cytolytic T Lymphocytes and Natural Killer Cells," <i>Biochem. Pharmacol.</i> 59:317-320 (2000)					
	34	LECHNER et al., "Nestin-Positive Progenitor Cells Derived from Adult Human Pancreatic Islets of Langerhans Contain Side Population (SP) Cells Defined by Expression of the ABCG2 (BCRP1) ATP-Binding Cassette Transporter," <i>Biochem. Biophys. Res. Comm.</i> 293:670-674 (2002)					
	35	LEE et al., "Isolation of cDNA for a Human Granulocyte-Macrophage Colony-Stimulating Factor by Functional Expression in Mammalian Cells," <i>Proc. Natl. Acad. Sci. USA</i> 82:4360-4364 (1985)					
	36	LOUIS et al., "Decrease in Systemic Tolerance to Fed Ovalbumin in Indomethacin-Treated Mice," <i>Int. Archives Allergy Immunology</i> 109:21-26 (1996)					
	37	MAIER et al., "Unique Molecular Surface Features of <i>in vivo</i> Tolerized T Cells," <i>Proc. Natl. Acad. Sci. USA</i> 95:4499-4503 (1998)					
	38	MIYATAKE et al., "Structure of the Chromosomal Gene for Granulocyte-Macrophage Colony Stimulating Factor: Comparison of the Mouse and Human Genes," <i>EMBO J.</i> 4(10):2561-2568 (1985)					
	39	MÜLLER et al., "Subtypes of the Type 2 cAMP Phosphodiesterases: Structure, Regulation and Selective Inhibition," <i>Trends Pharmacol. Sci.</i> 17:294-298 (1996)					
	40	NEWBERRY et al., "Cyclooxygenase-2-Dependent Arachidonic Acid Metabolites are Essential Modulators of the Intestinal Immune Response to Dietary Antigen," <i>Nature Medicine</i> 5:900-906 (1999)					
	41	OCHOA et al., "T-Cell Release of Granulysin Contributes to Host Defense in Leprosy," <i>Nature Medicine</i> 7:174-179 (2001)					
	42	PALFREYMAN & SOUNESS, "Phosphodiesterase Type IV Inhibitors," <i>Prog. Med. Chem.</i> 33:1-52 (1996)					
	43	PFENDLER & KAWASE, "The Potential of Stem Cells," <i>Obstetrical &amp; Gynecological Survey</i> 58:197-208 (2003)					
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	44	RITTIÉ et al., "Malondialdehyde Binding to Proteins Dramatically Alters Fibroblast Functions," <i>J. Cell. Physiol.</i> 191:227-236 (2002)					
	45	RITZ et al., "On the Generation of Allergic Airway Diseases: From GM-CSF to Kyoto," <i>Trends Immunol.</i> 23(8):396-402 (2002)					
	46	ROBERTSON et al., "Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Targets Myeloid Leukocytes in the Uterus During the Post-Mating Inflammatory Response in Mice," <i>J. Reproductive Immunol.</i> 46:131-154 (2000)					
	47	RUGTVEIT et al., "Differential Distribution of B7.1 (CD80) and B7.2 (CD86) Costimulatory Molecules on Mucosal Macrophage Subsets in Human Inflammatory Bowel Disease (IBD)," <i>Clin. Exp. Immunol.</i> 110:104-113 (1997)					
	48	SCHEUER et al., "Interference with Tolerance Induction <i>in Vivo</i> by Inhibitors of Prostaglandin Synthesis," <i>Cellular Immunology</i> 104:409-418 (1987)					
	49	SCHWACHA et al., "Cyclooxygenase 2-Mediated Suppression of Macrophage Interleukin-12 Production After Thermal Injury," <i>Am. J. Physiol. Cell Physiol.</i> 282:C263-C270 (2002)					
	50	SMYTH et al., "Unlocking the Secrets of Cytotoxic Granule Proteins," <i>J. Leukoc. Biol.</i> 70:18-29 (2001)					
	51	STAFFORD & FELDMAN, "Chronic Pulmonary Inflammation and Other Therapeutic Applications of PDE IV Inhibitors," <i>Annual Reports in Medicinal Chemistry</i> , Ed. Bristol, Academic Press, NY. USA, Chapter 8, Vol. 31, pp.77-80 (1996)					
	52	STEM CELL INFORMATION, "Stem Cell Basics," The Official National Institutes of Health Resource for Stem Cell Research, at <a href="http://stemcells.nih.gov/infoCenter/stemCellBasics.asp">http://stemcells.nih.gov/infoCenter/stemCellBasics.asp</a>					
	53	STEM CELL INFORMATION, "11. Use of Genetically Modified Stem Cells in Experimental Gene Therapies," The Official National Institutes of Health Resource for Stem Cell Research, at <a href="http://stemcells.nih.gov/info/scireport/chapter11.asp">http://stemcells.nih.gov/info/scireport/chapter11.asp</a>					
	54	STRASSMANN et al., "Evidence for the Involvement of Interleukin 10 in the Differential Deactivation of Murine Peritoneal Macrophages by Prostaglandin E <sub>2</sub> ," <i>J. Exp. Med.</i> 180:2365-2370 (1994)					
	55	SU et al., "Platelet-Derived Growth Factor Promotes <i>ex vivo</i> Expansion of CD34 <sup>+</sup> Cells from Human Cord Blood and Enhances Long-Term Culture-Initiating Cells, Non-Obese Diabetic/Severe Combined Immunodeficient Repopulating Cells and Formation of Adherent Cells," <i>Br. J. Haematol.</i> 117:735-746 (2002)					
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	56	TEIXEIRA et al., "Phosphodiesterase (PDE)4 Inhibitors: Anti-Inflammatory Drugs of the Future?" <i>Trends Pharmacol. Sci.</i> 18:164-170 (1997)					
	57	"The 'Edmonton' Protocol," at <a href="http://www.diabetes.org.uk/islets/trans/edmonton.htm">http://www.diabetes.org.uk/islets/trans/edmonton.htm</a>					
	58	VAN DER POUW KRAAN et al., "Prostaglandin-E2 Is a Potent Inhibitor of Human Interleukin 12 Production," <i>J. Exp. Med.</i> 181:775-779 (1995)					
	59	WONG et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," <i>Science</i> 228(4701):810-815 (1985)					
	60	YANG et al., "In vitro Trans-Differentiation of Adult Hepatic Stem Cells Into Pancreatic Endocrine Hormone-Producing Cells," <i>Proc. Acad. Natl. Sci. USA</i> 99:8078-8083 (2002)					
	61	ZHAO et al., "A Human Peripheral Blood Monocyte-Derived Subset Acts as Pluripotent Stem Cells," <i>Proc. Natl. Acad. Sci. USA</i> 100:2426-2431 (2003)					
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